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(54) A process for the preparation of a low-calorie nutritional preparation.

(57) A process is described for the preparation of a low-calorie nutritional preparation, in particular for use as the main or sole nutrition in the treatment of adipositas, in which sources of protein, carbohydrate and fat, and optionally flavouring agents, preservatives, vitamins, minerals and other usual additives are combined. By using soya protein concentrate, agglomerated skimmed milk powder and soya phospholipid as sources of protein, carbohydrate and fat, a preparation is achieved which may readily be stirred up in water to a homogeneous consistency and formulated into a product without unpleasant taste.

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### A PROCESS FOR THE PREPARATION OF A LOW-CALORIE NUTRITIONAL PREPARATION.

The present invention relates to a process for the preparation of a low-calorie nutritional preparation, especially for use as the main or sole nutrition in the treatment of adipositas.

Adipositas is a widespread problem in large parts of the world. At the same time, the increased health consciousness has stimulated the interest in "keeping the slim line". A large number of different diets have therefore been put on the market aiming at a rapid weight reduction.

Some of these diets must be considered unwarrantable seen from a nutritional point of view as they are based on a very unbalanced intake of nutrients which very quickly will result in deficiency of essential nutrients.

Other diets are based on nutritional preparations being composed in such a way that at a low calorie content they supply the necessary proteins, vitamins and minerals. These preparations are in the form of powders containing sources of protein, carbohydrate and fat, and optionally flavouring agents, preservatives, vitamins, minerals and other conventional additives. Before intake, the powders are stirred up in water and then taken as a drink or a gruel. However, the known preparations suffer from a number of deficiencies. The known powders can only with difficulty be stirred up in water so that the stirred up preparations will have a lumpy and gritty consistency which makes them very unpleasant to take. At the same time, sedimentation occurs very quickly, involving the risk that essential components such as sparingly soluble minerals are not taken in, but remain as a sediment at the bottom of the glass. Finally, the preparations have an unpleasant tang which persists as an after-taste a long time after the preparation has been taken. These disadvantages have the effect that many persons break off the diet too soon.

A very comprehensive work has therefore been carried out to provide a nutritional powder of the above-mentioned nature which has improved consistency, solubility/dispersibility and taste with a view to making the product more acceptable to the consumer. As a result hereof, it has been discovered that a nutritional preparation having a strongly improved consistency and solubility/dispersibility can be achieved by a process for the preparation of a low-calorie nutritional preparation, especially to be used as the essential or sole nutrition in the treatment of adipositas, in which sources of protein, carbohydrate and fat, and optionally flavouring agents, preservatives, vitamins, minerals and other conventional additives such as emulsifiers and antioxidants, are combined, when soya protein concentrate, agglomerated skimmed milk powder and

soya phospholipid are used as sources of protein, carbohydrate and fat.

It is preferable to use a soya protein concentrate prepared on the basis of shelled soya beans, and equally it is preferred to use a soya protein concentrate substantially freed from water-soluble carbohydrates and flavouring agents. Such products have been found to have a high degree of solubility, a high water binding capacity and excellent fat emulsification properties. Besides, they are of neutral taste.

An additional improvement of the taste and consistency of the preparation is achieved by adding lecithinized cocoa.

The employed lecithinized cocoa will typically contain 2-8 weight% of lecithin, preferably 3-7 weight% of lecithin, and most preferably 4-6 weight% of lecithin. The lecithinized cocoa is preferably included in an amount corresponding to 35-65 weight% of the skimmed milk powder.

The weight ratio between protein, carbohydrate and fat of the prepared product will typically be 40-60 parts of protein to 15-35 parts of carbohydrate to 2.0-6.0 parts of fat, and preferably 45-55 parts of protein to 20-30 parts of carbohydrate to 3.0-6.0 parts of fat. However, also other amounts can be used, if appropriate for a desired end use.

It is furthermore preferable that the employed components contain a certain amount of fibres, such as 3-8 parts by weight of fibres. These fibres may wholly or partly be derived from the soya protein concentrate and the cocoa.

It has furthermore been found that a further improvement of the taste of the product can be achieved if vitamins and minerals are not included in the powder but administered in tablet form, which in addition gives a safer dosage of these essential components. Therefore, according to a preferred embodiment of the process of the invention vitamins and minerals are not added in addition to those naturally forming part of the employed components or in addition to such being necessary in view of the formulation technique used.

For the purpose of a simple and safe dosage, the low-calorie nutritional preparation is preferably packed in a package intended for being able to cover the total nutrition requirement for a defined period of time, for example a week, whereby the preparation is divided up into suitable sub-units of a daily dose, preferably five sub-units per daily dose, which are packed separately before packing into the package, or the package is provided with means for apportioning of such sub-unit, and furthermore a number of daily doses of vitamins and minerals in tablet form corresponding to the chosen

time period are enclosed in the package.

Adipositas is often accompanied by an increased fatty content in the blood. It is therefore desirable to alter the lipid profile. Fish oils containing polyunsaturated fatty acids ( $\omega$ -3 fatty acids) have been found to have a favourable influence on the lipid profile, as they lower the total serum cholesterol content while at the same time increasing the HDL/LDL ratio. This activity is desirable also from a general health view. In the package mentioned above, there is, therefore, also preferably included a number of daily doses of fish oil containing polyunsaturated fatty acids in capsule form, corresponding to the chosen time period.

The fish oil may also be added in microencapsulated form and as such be admixed to the powder.

The chemical composition of the employed agglomerated skimmed milk powder corresponds to a non-agglomerated skimmed milk powder, but the altered physical form makes the product very readily soluble in water.

The soya phospholipid serves as a source for unsaturated fatty acids, especially linolic and linolenic acid, and it is furthermore assumed that it acts as emulsifier and stabilizing agent when the nutritional powder is stirred up in water.

The amount of energy in a daily dose will normally be from 300-600 Kcals (1260-2520 kilojoule), preferably from 350-500 Kcals (1470-2100 kilojoule) and most preferably 400-450 Kcals (1680-1890 kilojoule).

As mentioned above, the preparation is in particular intended for use as the main or sole nutrition in the treatment of adipositas, but the preparation may, of course, also be used as a nutritional supplement, f. ex. in the treatment of anorexia, where it is difficult to secure the requisite supply of essential nutritional components through food intake.

In a presently preferred composition the powder consists of abt. 60 parts by weight of soya protein concentrate, abt. 25 parts by weight of agglomerated skimmed milk powder, abt. 2.0 parts by weight of soya phospholipid, abt. 12.5 parts by weight of lecithinized cocoa having a lecithin content of abt. 5% and abt. 0.2 parts by weight of vanillin to which may be added 0.2 parts by weight of aspartame as sweetening agent, preferably 0.16 parts by weight of aspartame. In addition, abt. 1.6 parts by weight of NaCl is added for optimization of the electrolyte content.

122 g of this powder corresponds to a daily dose. Such dosis supplies to the body 61.3 g protein containing the essential aminoacids, 30.5 g carbohydrate, 6.0 g fat and 5.4 g fibres. The daily dose is divided into five portions which are stirred up in water and administered at intervals of 3-4 hours, so that the intake is spread as evenly as

possible over 24 hours. It is important that the preparation be taken at such regular intervals as possible, as it has been proved that the metabolism is increased during each meal.

Vitamins and minerals are dosed within the limits laid down by the health authorities and are administered 1 time daily in tablet form. On basis of these norms each tablet contains, in the presently preferred embodiment, vitamins and minerals as follows, in supplement of the vitamins and minerals contained in the nutritional powder:

Vitamins: Vit. A 3000 IU, vit. D<sub>3</sub> 200 IU, vit. E 10 mg, vit. B<sub>1</sub> 1.5 mg, vit. B<sub>2</sub> 1.5 mg, niacinamide 15 mg, vit. B<sub>6</sub> 2.0 mg, folic acid 100 µg, vit. B<sub>12</sub> 4 µg, pantothenic acid 4 mg and vit. C 60 mg.

Minerals: Iron 10 mg, zinc 10 mg, iodine 75 µg, copper 1.5 mg, manganese 1 mg, chromium 75 µg and selenium 75 µg.

Each fish oil capsule contains one gram of fish oil concentrate which contains 180 mg EPA (eicosapentaenoic acid) and 120 mg DNA (decosahexaenoic acid) corresponding to more than 30% omega-3 fatty acids.

A daily dose of the nutritional powder contains a total of abt. 430 Kcals. (1806 kilojoule).

Of 80 patients, approximately evenly distributed on men and women, who went through with an 8 weeks diet of a preferred composition as stated above, the men achieved an average weight reduction of 19.4 kg with weight losses varying from 10.5 - 30.6 kg, while the women achieved an average weight loss of 12.7 kg, with weight losses varying from 7.8 - 19.5 kg. None of them gave up the diet, but two had meals beside the diet (the man and the woman with the lowest weight loss, respectively), and about half of them occasionally supplemented with vegetables. All the patients went through very comprehensive laboratory tests before and after the diet, and no essential side-effects were found. In abt. 5% of the patients there was a slight rise of the uric acid content which was quickly normalized after the diet. The treatment regimen had a favourable effect on the cholesterol and glucose level. The invention is further illustrated by the following examples.

#### Example 1

The following components were mixed per 1000 g of powder.

590 g "Danpro 5" <sup>1)</sup>  
 247 g agglomerated skimmed milk powder <sup>2)</sup>  
 123 g lecithinized cocoa 10/12 DP from Bensdorp <sup>3)</sup>  
 20.5 g "Epikuron 100 SPI" <sup>4)</sup>  
 ) 1.9 g vanillin  
 1.6 g aspartame

16 g NaCl

1) A soya protein concentrate prepared from shelled soya beans and freed from undesired components such as water-soluble carbohydrates, flavouring agents and growth inhibiting agents. The concentrate typically contains 66.0% protein, 17.0% carbohydrate, 8.0% water, 5.6% ashes, 4.0% wood substance and 1.4% fat.

2) Typically contains 34.8 g protein, 1.4 g fat, 52.7 g carbohydrate, 7.8 g ashes, and max. 4.0 g water per 100 g of product.

3) The product contains 5% lecithin, and the cocoa part typically contains 23% protein, 35% carbohydrate, 18% cellulose, 2.5% theobromine and max. 5% water.

4) A total complex of isolated soya phospholipids containing 57-61% fatty acids, of which 62-68% are polyunsaturated distributed on 56-60% linolic acid and 6-8% linolenic acid.

The powder was packed in envelopes of 24 g each.

The invention has in the foregoing been described by means of specific embodiments, but it will be understood that various changes and modifications may be performed without deviating from the scope and spirit of the invention.

#### Claims

1. A process for the preparation of a low-calorie nutritional preparation, especially for use as the main or sole nutrition in the treatment of adipositas, in which sources of protein, carbohydrate and fat and optionally flavouring agents, preservatives, vitamins, minerals and other conventional additives are combined, CHARACTERIZED in that soya protein concentrate, agglomerated skimmed milk powder and soya phospholipid are used as sources of protein, carbohydrate and fat.
2. A process according to Claim 1, CHARACTERIZED in that the employed soya protein concentrate is prepared from shelled soya beans.
3. A process according to Claim 1 or 2, CHARACTERIZED in that the employed soya protein concentrate substantially is freed from water-soluble carbohydrates and flavouring agents.
4. A process according to one or more of the Claims 1-3, CHARACTERIZED by additionally including lecithinated cocoa, said lecithinated cocoa preferably containing 2-8 weight% of lecithin, and most preferably 4-6 weight% of lecithin, and preferably including said lecithinated cocoa in an amount corresponding to 35-65 weight% of the skimmed milk powder.
5. A process according to one or more of the preceding claims, CHARACTERIZED in that the weight ratio between protein, carbohydrate and fat

in the prepared preparation is 40-60 parts of protein to 15-35 parts of carbohydrate to 2.0-6.0 parts of fat, preferably 45-55 parts of protein to 20-30 parts of carbohydrate to 3.0-6.0 parts of fat.

6. A process according to one or more of the preceding claims, CHARACTERIZED in that vitamins and minerals are not added in addition to those naturally occurring in the employed components or in addition to such being necessary in view of the formulation technique used.
7. A process according to one or more of the preceding claims, CHARACTERIZED in that the employed components contain a total of 3-8 parts by weight of fibres.
8. A process according to one or more of the preceding claims, CHARACTERIZED by additionally including fish oil containing polyunsaturated fatty acids in capsule form.
9. A process according to Claim 8, CHARACTERIZED in that the fish oil is included in microencapsulated form.
10. A process according to one or more of the preceding claims, CHARACTERIZED in that the low-calorie nutritional preparation is packed in a package intended for being able to cover the total nourishment requirement for a defined period of time, for example a week, the preparation being divided into suitable sub-units of a daily dose, preferably 5 sub-units per daily dose, which are packed separately prior to packing in the package, or the package is provided with means for apportioning of such sub-unit, and in that a number of daily doses of vitamins and minerals in tablet form corresponding to the chosen time period are packed in the package, and optionally a number of daily doses of fish oil containing polyunsaturated fatty acids in capsule form corresponding to said time period.

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## EUROPEAN SEARCH REPORT

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EP 90 61 0067

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. CL.5)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X	US-A-3 976 800 (R. DEININGER ET AL.)  * column 3, line 17 ~ line 20; claims 1-8; example 4 * * column 3, line 50 ~ column 4, line 31 *	1,2,3,6, 10	A23L1/305 A23L1/30 A23L1/308 A23L1/09
A	---	4,5,7-9	
X	WO-A-8 603 380 (BOEHRINGER BIOCHEMIA) * claims 1,2,3,5,6,7; example 7 *	7,10	
Y	---	8,9	
Y	EP-A-0 336 662 (CLINICAL TECHNOLOGIES ASSOCIATES ) * claim 1 *	8,9	
X	FR-A-2 375 834 (M. SIMAN)  * claims; example 1 *	1,2,5,6, 7	
A	EP-A-0 147 699 (NESTLE) * the whole document *	1-10	TECHNICAL FIELDS SEARCHED (Int. CL.5)
A	WO-A-8 002 226 (ELAINE POWERS NUTRITION) * the whole document *	1-10	A23L
<p>The present search report has been drawn up for all claims</p>			
Place of search THE HAGUE	Date of completion of the search 19 MARCH 1992	Examiner VAN MOER A. M. J.	
<b>CATEGORY OF CITED DOCUMENTS</b> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			
T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons  A : member of the same patent family, corresponding document			